

General

Guideline Title

Management of resectable stage IV primary cutaneous melanoma without nodal disease.

Bibliographic Source(s)

Alberta Provincial Cutaneous Tumour Team. Management of resectable stage IV primary cutaneous melanoma without nodal disease. Edmonton (Alberta): CancerControl Alberta; 2013 Feb. 9 p. (Clinical practice guideline; no. CU-009). [25 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Alberta Provincial Cutaneous Tumour Team. Management of resectable stage IV primary cutaneous melanoma without nodal disease. Edmonton (Alberta): Alberta Health Services, Cancer Care; 2010 May. 8 p. (Clinical practice guideline; no. CU-009).

Recommendations

Major Recommendations

For staging please refer to the Appendix in the original guideline document.

Primary Treatment

- Minimum work up should include computed tomography (CT) scan of the head, chest, abdomen and pelvis, or CT positron emission tomography (PET) scan, or either of the above with brain magnetic resonance imaging (MRI).
- Enrolment in a clinical trial is preferred.
- Resection
 - Complete resection results in a 5% long-term complete remission or cure rate and may contribute greatly to the quality of life.
 - If primary chemotherapy is used, consideration should be given to subsequent resection.

Systemic Therapy

- Options include:
 - Enrolment in a clinical trial (preferred)
 - Observation
- Following resection, a number of systemic therapies have been investigated (e.g., interferon-alpha [IFN-alpha], dacarbazine, temozolomide, high-dose interleukin-2 [IL-2], combination chemotherapy with cisplatin or vinblastine with or without IL-1 and IFN-alpha, and paclitaxel alone or in combination with platinum-based chemotherapy); however, no convincing disease-free survival or overall survival benefits have

been documented.

- Following systemic therapy, scans should be repeated.
 - If scans are negative for other disease, resect as necessary. If there is no further evidence of disease, consider clinical trial OR IFN-alpha OR observation. If there is residual disease, treat as disseminated (unresectable) disease (e.g., additional systemic therapy, surgical resection, or radiation for palliative care and symptom management).
 - If scans are positive for other disease, treat as disseminated (unresectable) disease.

Clinical Algorithm(s)

An algorithm titled "Algorithm for the Management of Melanoma Stage IV" is provided on the [Alberta Health Services Web site](#)

Scope

Disease/Condition(s)

Resectable stage IV primary cutaneous melanoma without nodal disease

Guideline Category

Management

Treatment

Clinical Specialty

Dermatology

Oncology

Radiation Oncology

Surgery

Intended Users

Physicians

Guideline Objective(s)

To outline treatment and management strategies for patients with resectable stage IV primary cutaneous melanoma without nodal disease

Target Population

Patients with resectable stage IV primary cutaneous melanoma without nodal disease

Interventions and Practices Considered

1. Computed tomography (CT) scan of the head, chest, abdomen and pelvis
2. CT positron emission tomography (PET) scan

3. Brain magnetic resonance imaging (MRI)
4. Enrolment in a clinical trial
5. Complete resection
6. Primary chemotherapy followed by resection
7. Observation
8. Systemic therapy following resection
 - Interferon-alpha (IFN-alpha)
 - Dacarbazine
 - Temozolomide
 - High-dose interleukin-2 (IL-2)
 - Combination chemotherapy with cisplatin or vinblastine with or without IL-1 and IFN-alpha
 - Paclitaxel alone or in combination with platinum-based chemotherapy
9. Repeated scans following systemic therapy to direct further management

Major Outcomes Considered

- Response rates
- Survival rate (overall, progression-free, 5-year)
- Morbidity
- Quality of life

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Research Questions

Specific research questions to be addressed by the guideline document were formulated by the guideline lead(s) and Knowledge Management (KM) Specialist using the PICO question format (Patient or Population, Intervention, Comparisons, Outcomes).

Guideline Question

What are the best treatment and management options for improving the survival and management of symptoms in patients with resectable Stage IV primary cutaneous melanoma?

Search Strategy

The MEDLINE, Cochrane, American Society of Clinical Oncology (ASCO) Abstracts and Proceedings, and CANCERLIT databases were searched (1985 through November 2009) for clinical trials. Search terms included: "resectable" or "stage IV" or "advanced" or "metastatic" and "primary cutaneous melanoma" AND "surgery" or "metastectomy" or "radiation therapy" or "chemotherapy" or "interleukin" or "interferon" or "taxane" or "supportive care" or "palliative care." A total of 82 clinical trials (limits: human and English language) were returned, from which 29 documents were selected. In addition, the National Guideline Clearinghouse and individual guideline organizations were searched for practice guidelines relevant to this topic.

For the 2013 update of the guideline, PubMed was searched for evidence on resectable stage IV melanoma. The search term "melanoma" was used and results were limited to clinical trials, published between December 2009 and January 2013. Citations were hand-searched for studies pertaining to in-transit disease.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Not stated

Rating Scheme for the Strength of the Evidence

Not applicable

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Evidence was selected and reviewed by a working group comprised of members from the Alberta Provincial Cutaneous Tumour Team and a Knowledge Management (KM) Specialist from the Guideline Utilization Resource Unit (GURU). A detailed description of the methodology followed during the guideline development process can be found in the [Guideline Utilization Resource Unit Handbook](#) (see the "Availability of Companion Documents" field).

Evidence Tables

Evidence tables containing the first author, year of publication, patient group/stage of disease, methodology, and main outcomes of interest are assembled using the studies identified in the literature search. Existing guidelines on the topic are assessed by the KM Specialist using portions of the Appraisal of Guidelines Research and Evaluation (AGREE) II instrument (<http://www.agreetrust.org>) and those meeting the minimum requirements are included in the evidence document. Due to limited resources, GURU does not regularly employ the use of multiple reviewers to rank the level of evidence; rather, the methodology portion of the evidence table contains the pertinent information required for the reader to judge for himself the quality of the studies.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Formulating Recommendations

The working group members formulate the guideline recommendations based on the evidence synthesized by the Knowledge Management (KM) Specialist during the planning process, blended with expert clinical interpretation of the evidence. As detailed in the [Guideline Utilization Resource Unit Handbook](#) (see the "Availability of Companion Documents" field), the working group members may decide to adopt the recommendations of another institution without any revisions, adapt the recommendations of another institution or institutions to better reflect local practices, or develop their own set of recommendations by adapting some, but not all, recommendations from different guidelines.

The degree to which a recommendation is based on expert opinion of the working group and/or the Provincial Tumour Team members is explicitly stated in the guideline recommendations. Similar to the American Society of Clinical Oncology (ASCO) methodology for formulating guideline recommendations, the Guideline Utilization Resource Unit does not use formal rating schemes for describing the strength of the recommendations, but rather describes, in conventional and explicit language, the type and quality of the research and existing guidelines that were taken into consideration when formulating the recommendations.

Following a review of the evidence by the Alberta Provincial Cutaneous Tumour Team, no major changes to the recommendations were made.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

A formal cost analysis was not performed and published analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

This guideline was reviewed and endorsed by the Alberta Provincial Cutaneous Tumour Team.

When the draft guideline document has been completed, revised, and reviewed by the Knowledge Management (KM) Specialist and the working group members, it is sent to all members of the Provincial Tumour Team for review and comment. This step ensures that those intended to use the guideline have the opportunity to review the document and identify potential difficulties for implementation before the guideline is finalized.

Depending on the size of the document, and the number of people it is sent to for review, a deadline of one to two weeks will usually be given to submit any feedback. Ideally, this review will occur prior to the annual Provincial Tumour Team meeting, and a discussion of the proposed edits will take place at the meeting. The working group members will then make final revisions to the document based on the received feedback, as appropriate. Once the guideline is finalized, it will be officially endorsed by the Provincial Tumour Team Lead and the Executive Director of Provincial Tumour Programs.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The recommendations were developed based on evidence from clinical trials as well as existing guidelines.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate management of resectable stage IV primary cutaneous melanoma without nodal disease

Potential Harms

- Because chemoimmunotherapy is significantly more toxic (grade 3+ events) than chemotherapy, it should be used only in select patients (i.e., those with good performance status [Eastern Cooperative Oncology Group (ECOG) 0-1] and normal lactate dehydrogenase levels).
- Toxicity of chemotherapy

Qualifying Statements

Qualifying Statements

The recommendations contained in this guideline are a consensus of the Alberta Provincial Cutaneous Tumour Team and are a synthesis of currently accepted approaches to management, derived from a review of relevant scientific literature. Clinicians applying these guidelines should, in consultation with the patient, use independent medical judgment in the context of individual clinical circumstances to direct care.

Implementation of the Guideline

Description of Implementation Strategy

- Present the guideline at the local and provincial tumour team meetings and weekly rounds.
- Post the guideline on the Alberta Health Services website.
- Send an electronic notification of the new guideline to all members of CancerControl Alberta.

Implementation Tools

Clinical Algorithm

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Identifying Information and Availability

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

Guideline Developer(s)

CancerControl Alberta - State/Local Government Agency [Non-U.S.]

Source(s) of Funding

CancerControl Alberta

There was no direct industry involvement in the development or dissemination of this guideline.

Guideline Committee

Alberta Provincial Cutaneous Tumour Team

Composition of Group That Authored the Guideline

Members of the Alberta Provincial Cutaneous Tumour Team include medical oncologists, radiation oncologists, surgical oncologists, dermatologists, nurses, pathologists, and pharmacists.

Financial Disclosures/Conflicts of Interest

Participation of members of the Alberta Provincial Cutaneous Tumour Team in the development of this guideline has been voluntary and the authors have not been remunerated for their contributions. CancerControl Alberta recognizes that although industry support of research, education and other areas is necessary in order to advance patient care, such support may lead to potential conflicts of interest. Some members of the Alberta Provincial Cutaneous Tumour Team are involved in research funded by industry or have other such potential conflicts of interest. However the developers of this guideline are satisfied it was developed in an unbiased manner.

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Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the [Alberta Health Services Web site](#) .

Availability of Companion Documents

The following is available:

- Guideline utilization resource unit handbook. Edmonton (Alberta): CancerControl Alberta; 2013 Jan. 5 p. Electronic copies: Available in Portable Document Format (PDF) from the [Alberta Health Services Web site](#) .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on December 31, 2012. The information was verified on February 5, 2013. This summary was updated by ECRI Institute on April 28, 2014. The updated information was verified by the guideline developer on May 23, 2014.

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